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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/386,266	08/31/1999	DAVID J. BRAYDEN	99.1080.US	1219

7590 12/27/2005

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EXAMINER	
DEVI, SARVAMANGALA J N	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 12/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Interview Summary	Application No.	Applicant(s)	
	09/386,266	BRAYDEN, DAVID J.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

All participants (applicant, applicant's representative, PTO personnel):

(1) *S. Devi (PTO)*. (3)_____.

(2) *Jonathan Dermott*. (4)_____.

Date of Interview: *20 December 2005*.

Type: a)☒ Telephonic b)☐ Video Conference
c)☐ Personal [copy given to: 1)☐ applicant 2)☐ applicant's representative]

Exhibit shown or demonstration conducted: d)☒ Yes e)☐ No.
If Yes, brief description: *Proposed claim amendment submitted by facsimile on 12/19/05*.

Claim(s) discussed: *All of record, claims 35, 41, 46 and 47 in particular*.

Identification of prior art discussed: _____.

Agreement with respect to the claims f)☐ was reached. g)☒ was not reached. h)☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *See Continuation Sheet*.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

SD - 12/20/05
S. DEVI, PH.D.
PRIMARY EXAMINER

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

_____
Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)
In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Mr. Dermott indicated that the term 'about' has been deleted in the proposed base claims, and the limitation 'at least one antigen' has been added to address 35 USC 112, second paragraph issues. He stated that claim 46 is deleted. He pointed to the recitation '2.2' at line 7 of page 15, and to Tables 1 and 2 of the specification and explained how he interprets claim 47. The Examiner pointed that Tables 1 and 2 and the first paragraph of page 15 of the specification do not support claim 47 which is drawn to a vaccine formulation comprising at least two subpopulations of microparticles having the recited average diameter, each comprising a different antigen. Mr. Dermott was reminded that the antigen combination of PTd plus FHA of Example 7 is a mixture of PTd antigen entrapped in PLGA microparticles having the average diameter of 2.4, 3.2 and 3.3μm and FHA antigen entrapped in PLGA microparticles having the average diameter of 3.0 and 4.3μm. Mr Dermott was informed that the limitation added at the end of the currently proposed claim 35 appears to include multiple microparticle size ranges and that a more careful evaluation for new matter would be performed upon a closer review of the specification. Mr. Dermott asked for a second interview in the presence of the supervisor.

SD - 12/20/05
S. DEVI, PH.D.
PRIMARY EXAMINER

FACSIMILE COVER SHEET

Law Offices of
SYNNESTVEDT & LECHNER LLP
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PLEASE DELIVER THE FACSIMILE TRANSMITTED HEREWITH TO:

NAME: Examiner Sarvamangala J.N. Devi

FROM: Jonathan M. Dermott, Reg. No. 48,608

RE: Appl. No. 09/386,266

S&L Docket No. P26,485-A USA

A total of 3 **pages, including this cover sheet, will be transmitted.**

Confirmation copy sent: ___ Yes XX No

Name of Operator: Jonathan M. Dermott

Date: December 19, 2005

Facsimile number of recipient: 1 (571) 273-0854

Notes:

Dear Examiner Devi,

Attached are proposed claim amendments to assist us in our interview scheduled for 10:00am, tomorrow, December 20, 2005. I look forward to our discussion.

Regards, Jon Dermott

Amendments to the Claims

1 to 34. (Canceled).

35. (Currently amended) A method of inducing a T_H1 polarized immune response to at least one antigen comprising parenterally administering to a subject microparticles comprising said at least one antigen entrapped or encapsulated in a biodegradable polymer, wherein said microparticles are sized such that the average diameter of said microparticles is from ~~about~~ 2.2 μm to ~~about~~ 4.3 μm and wherein the microparticles are sized such that at least 50% of the microparticles are less than 5 μm.

36. (Previously presented) The method of Claim 35, wherein the microparticles are sized such that at least 50% of the microparticles are less than 3 μm.

37. (Previously presented) The method of Claim 35, wherein the biodegradable polymer comprises a copolymer of lactic acid and glycolic acid or enantiomers thereof.

38. (Previously presented) The method of Claim 35, wherein the microparticles are formed using a solvent evaporation method.

39. (Previously presented) The method of Claim 35, wherein the at least one antigen comprises a *B. pertussis* antigen.

40. (Previously presented) The method of Claim 35, wherein the parenteral administration is selected from the group consisting of intraperitoneal administration, subcutaneous administration and intramuscular administration.

41. (Currently amended) A vaccine formulation for enhancing a T_H1 immune response to at least one antigen and adapted for parenteral administration comprising a pharmaceutically acceptable carrier and a pharmaceutically effective amount of microparticles comprising said at least one antigen entrapped or encapsulated in a biodegradable polymer, wherein said microparticles are sized such that the average diameter of said microparticles is from ~~about~~

2.2 μm to ~~about~~ 4.3 μm and wherein the microparticles are sized such that at least 50% of the microparticles are less than 5 μm.

42. (Currently amended) The vaccine formulation of Claim 41, wherein the microparticles are sized such that at least 50% of the microparticles are less than 3 μm ~~m~~.

43. (Previously presented) The vaccine formulation of Claim 41, wherein the biodegradable polymer comprises a copolymer of lactic acid and glycolic acid or enantiomers thereof.

44. (Previously presented) The vaccine formulation of Claim 41, wherein the microparticles are formed using a solvent evaporation method.

45. (Previously presented) The vaccine formulation of Claim 41, wherein the at least one antigen comprises a *B. pertussis* antigen.

46. (Canceled)

47. (Currently amended) A vaccine formulation for enhancing a T_H1 immune response to at least one antigen and adapted for parenteral administration comprising a pharmaceutically acceptable carrier and a pharmaceutically effective amount of microparticles comprising at least 2 subpopulations of microparticles, each subpopulation comprising a different antigen, each antigen entrapped or encapsulated by a biodegradable polymer, wherein said microparticles are sized such that the average diameter of said microparticles is from ~~about~~ 2.2 μm to ~~about~~ 4.3 μm and wherein the microparticles are sized such that at least 50% of the microparticles are less than 5 μm.